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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,610	10/30/2003	Joseph M. Schmitt	TYHC:0143/FLE (P0277R-02)	9936
52144	7590	10/26/2006	EXAMINER	
FLETCHER YODER (TYCO INTERNATIONAL, LTD.) P.O. BOX 692289 HOUSTON, TX 77269-2289			LIN, JACK	
			ART UNIT	PAPER NUMBER
			3768	

DATE MAILED: 10/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/699,610

Applicant(s)

SCHMITT ET AL.

Examiner

Jack Lin

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on October 10, 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 28-43 is/are allowed.
- 6) ☒ Claim(s) 1-7 and 13-24 is/are rejected.
- 7) ☒ Claim(s) 8-12 and 25-27 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/23/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Invention I, Species A in the reply filed on October 10, 2006 is acknowledged.
2. Claims 40-43 are directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(B), claims 40-43, directed to the process of making or using an allowable product, previously withdrawn from consideration as a result of a restriction requirement, are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Because all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, **the restriction requirement as set forth in the Office action mailed on August 31, 2006 is hereby withdrawn.** In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on January 23, 2006 is acknowledged. The references listed therein have been considered.

Claim Objections

4. Claims 29 and 37 are objected to because of the following informalities: Line 6 of both Claims 29 and 37 contain three square symbols that appear to be in error. Appropriate correction is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-6 and 13-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Wenzel et al. (US Patent 6,442,408 – cited by applicant). Wenzel et al. discloses the same invention including a probe housing (column 4, lines 4-8), light emission optics (column 3, lines 64-67), light detection optics (column 4, lines 1-2), and a processing device (column 4, line 63) configured to compute water content of fat-free tissue (column 4, lines 46-48).

Regarding Claim 2, Wenzel et al. discloses a device that quantifies the stratum corneum hydration (column 3, lines 50-51) which is inherently a bone-free and fat-free tissue.

Regarding Claim 3, Wenzel et al. discloses a display device (column 6, line 63).

Regarding Claim 4, Wenzel et al. discloses the light emission and detection optics spaced 1 mm apart (column 4, lines 23-27).

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Regarding Claims 5 and 6, Wenzel et al. discloses the device monitoring the metric intermittently and continuously (column 8, lines 25-41).

Regarding Claims 13-17, Wenzel et al. discloses choosing a plurality of wavelengths from the 950-1400 nm band (column 4, lines 30-31). In particular, Wenzel et al. discloses using a set of wavelengths including 1190 and 1280 nm (column 4, lines 30-31). Applicant admits in the specification that choosing a plurality of lights within the wavelength band of 950-1400 nm, and in particular 1180 and 1300 nm, would satisfy the claimed elements (page 6, line 33 – page 8, line 3).

Regarding Claims 18 and 19, Wenzel et al. discloses the device to operate in either the transmissive or reflective mode (column 4, lines 53-56).

Regarding Claim 20, Wenzel et al. discloses the light emission and detection optics placed in a remote unit and optical fibers (column 4, lines 4-11).

Regarding Claim 21, Wenzel et al. discloses light emitting diodes (column 3, line 67).

Regarding Claims 21-24, Wenzel et al. discloses receiving light of at least two sets of optical measurements where absorption in one set is primarily due to water and non-heme proteins and absorption in a second set is primarily due to water (column 4, lines 30-31 and applicant's specification page 5, paragraph 23) and comparing the at least two sets of optical measurements through the ratio of wavelength combinations and weighted summation of the ratio (column 7, line 1-62).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wenzel et al. as applied to claim 1 above, and further in view of Yamanishi (US Patent 5,933,226). Wenzel et al. discloses the invention substantially as claimed with the exception of a spring-loaded probe configured to automatically activate a display device when the spring-loaded probe is pressed against a tissue location. Yamanishi discloses a concentration measuring apparatus comprising a projection with a spring member as a means to cause a light source to emit light when the projection is pushed against a biasing force (column 3, lines 29-44). Therefore, it would have been obvious at to one having ordinary skill in the art at the time of the invention to have provided the apparatus of Wenzel et al. with a spring-loaded probe as disclosed by Yamanishi in order to have a means to automatically activate a device.

Allowable Subject Matter

9. Claims 8-12 and 25-27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. Claims 28-43 are allowed.

11. The following is a statement of reasons for the indication of allowable subject matter:

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Regarding Claims 8-12, the prior art does not teach or suggest a pressure transducer, a mechanism for mechanically minimizing the pressure, a mechanism for mechanically inducing pressure, or a mechanism for mechanically varying pressure in combination with the other claimed elements.

Regarding Claims 25-27, the prior art does not teach or suggest a processing device comparing at least two sets of optical measurements where a ratio of the at least two measurements provides a measure proportional to the difference between the fractions of water in the blood and surrounding tissue location in combination with the other claimed elements.

Regarding Claims 28-34 and 36-37, the prior art does not teach or suggest a processing device configured to measure and a method of measuring a body tissue metric wherein the body tissue metric comprises a quantified measure of a ratio of a difference between the water fraction in the blood and the water fraction in the extravascular tissue over the fractional volume concentration of hemoglobin in the blood in combination with the other claimed elements.

Regarding Claim 35, the prior art does not teach or suggest computing a water content metric where the water content metric is determined by the claimed equation in combination with the other claimed elements.

Regarding Claims 38-43, the prior art does not teach or suggest computing a physiological parameter where the parameter is determined by the claimed equation in combination with the other claimed elements.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jack Lin whose telephone number is (571) 272-7694. The examiner can normally be reached on Monday-Friday, 8:00 a.m. - 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on (571) 272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JL
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53 ERIC F. WINAKUR
PRIMARY EXAMINER